510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

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1. GENERAL INFORMATION

Trade Name	LIGAFIX® Resorbable Interference Screw
Common Name	Bone Fixation Screw
Classification Name	Screw, Fixation, Bone
Class	II
Product Code	HWC
CFR section	21CFR 888.3040
Device panel	Orthopedic
Legally marketed predicate devices	LIGAFIX® Resorbable Interference Screw K050407
Reason for special 510k	Extension of the range of products
Submitter	SCIENCE FOR BIOMATERIALS Sciences et Bio Matériaux ZI du Monge F 65100 LOURDES – FRANCE Owner operation Number : 9063735
Contact	Denis CLEMENT, General Manager Tel : +33 (0)5 62 42 21 01 Fax : +33 (0)5 62 42 21 00 e-mail : denis.clement@sbm-fr.com Regulatory contact: Idée Consulting (FRANCE) Isabelle DRUBAIX e-mail : idrubaix@nordnet.fr

2. DEVICE DESCRIPTION

LIGAFIX 30® resorbable cannulated screws are designed for the interference fixation of grafts in anterior cruciate ligament reconstruction.

LIGAFIX 30® interference screws are made of a ceramic (30% β-TCP) / polymer (70% Poly Lactic Acid -PLA) composite.

LIGAFIX 30® interference screws are supplied sterile and individually packaged in double heat sealed pouches.

3. INTENDED USE

LIGAFIX 30® interference screws are indicated for use in anterior cruciate ligament reconstruction to provide interference fixation of grafts.

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4. SUBSTANTIAL EQUIVALENCE

The modifications to LIGAFIX® Interference screw K050407 consist of additional size of screw together with the addition of a slightly modified design of the head of the screw.

The additional LIGAFIX® Interference screws have the same fundamental scientific technology, operating principle and intended use as previously cleared LIGAFIX® Interference screw K050407.

Summary preparation date: April 21, 2006

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Science For Bio Materials
% Mr. Denis Clement
General Manager
ZI du Monge
F 65100 Lourdes
FRANCE

JUL - 5 2006

Re: K061262
Trade/Device Name: LIGAFIX® RESORBABLE INTERFERENCE SCREW
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: June 26, 2006
Received: June 28, 2006

Dear Mr. Clement:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally

marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or 240-276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061262

Device Name: LIGAFIX® RESORBABLE INTERFERENCE SCREW

Indications for Use:

LIGAFIX® 30 is a cannulated, sterile, single-use, resorbable interference bone screw made of a mixture of tri calcium phosphate (30% β-TCP) and Poly Lactic Acid (70% PLA) designed for the interference fixation of grafts in anterior cruciate ligament reconstruction.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use No (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buchman for MKM

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(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K061262